SEP 23 2002

K022725

510(k) SUMMARY

Safety and Effectiveness

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

CRPex CRP Controls Level L, M, H

Submitter

Name,	Good Biotech Corp.
Address,	38 34th Rd. Taichung Industrial Park Taichung City 407 Taiwan R.O.C.
Telephone number,	+886-4-23596873
Contact person,	Victor Chiou
Preparation date	August 14, 2002

Device

Trade name,	CRPex CRP Controls Level L, M, H
Common name,	CRP Control Material
Classification name	C-reactive protein immunological test system (21CFR 866.5270)

Predicate Device

Trade name,	Roche CRP T Control N
510(k) number	K982087

Description

Good Biotech Corp. CRPex CRP Controls are intended to be used as the assayed quality control material for serum C-reactive protein (CRP) analysis. Each CRP Control contains certain level of human serum CRP to assist in monitoring the precision and accuracy of assay systems within the clinical range.

Measurement of C-reactive protein is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases.

Intended Use

Good Biotech Corp. CRPex CRP Controls are intended to be used as the assayed quality control material for serum C-reactive protein (CRP) analysis. For *in vitro* diagnostic use.

Substantial Equivalence

CRPex-HS CRP Controls and Roche CRP T Control N are both human serum based controls with assigned C-reactive protein concentration and intended for use in monitoring accuracy and precision in CRP analysis.

Item\Device	CRPex CRP Controls	Roche CRP T Control N
Matrix/Biological Sources	Liquid human serum	Liquid human serum
Concentration Range (mg/L)	Level L 1.28 – 1.92 Level M 4.54 – 6.81 Level H 46.82 – 70.23	3.44 – 4.66

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 23 2002

Mr. Victor Chiou
President
Good Biotech Corporation
38 34th Road
Taichung Industrial Park
407 Taichung City, Taiwan, R.O.C.

Re: k022725
Trade/Device Name: CRPex CRP Controls Level L, M, H
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed).
Regulatory Class: Class I
Product Code: JJX
Dated: August 14, 2002
Received: August 16, 2002

Dear Mr. Chiou:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K 022725

Device Name: CRPex CRP Controls Level L, M, H

Indications For Use:

Good Biotech Corp. CRPex CRP Controls are intended to be used as the assayed quality control material for serum C-reactive protein (CRP) analysis.
For In Vitro Diagnostic Use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

J P Reeves Acting Branch Chief D

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 022725